DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

9/27/d

**Food and Drug Administration**
**New Orleans District**
**Southeast Region**
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
Facsimile: 504-253-4560

May 10, 2001

**WARNING LETTER NO. 2001-NOL-21**

***FEDERAL EXPRESS***
**OVERNIGHT DELIVERY**

Mr. Kenneth J. Becnel, Owner
Becnel's Meat & Seafood Market
13851 Clifford Street
Vacherie, Louisiana 70090

Dear Mr. Becnel:

We inspected your firm, located at 13851 Clifford Street, Vacherie, Louisiana on April 18 - 20, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your cooked, peeled crawfish tail meat and cooked, picked crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

1. Your cooking processes for crawfish and crabs are inadequate because the cooked product internal temperatures do not consistently meet the 180° required minimum.

2. Your HACCP plan for "Fresh Peeled Crayfish Meat", "Frozen Crayfish Meat", "Frozen Crab Meat" and "Fresh Crab Meat" are inadequate in that:

   - The critical limits at the "Cooking" critical control point (CCP) are not adequate to control pathogen survival;

   - The critical limit of a minimum temperature needs to be included at the "Cooking" CCP;

   - The monitoring steps of What and How at the "Cooking" CCP do not address the correct factors which need to be monitored for the critical limit of cooking time;

- The adequacy of the minimum cook time and temperature has not been verified. This was previously brought to your attention in the Form FDA 483 issued September 20, 2000; and,

- You must implement the record keeping system listed in your HACCP plan. However, your firm did not record monitoring observations at the peeling and packing CCPs to control the pathogen hazards listed in your HACCP plan for crawfish meat.

3. You must implement the record keeping system listed in your HACCP plan. However, your firm did not record monitoring observations at the backing, picking, and packing CCPs to control the pathogen hazards listed in your HACCP plan for crabmeat. This deficiency was previously brought to your attention in the Form FDA 483 issued September 20, 2000.

4. You must implement the requirements listed in your HACCP plan. However, your firm did not consistently follow the minimum listed cook times in your HACCP plan for crawfish and crabmeat, take the internal temperatures of the cooked crawfish and crab product, and follow the maximum time for the crawfish to remain on the picking table.

5. You must implement the verification procedures listed in your HACCP plan. However, your firm did not follow the verification procedure of thermometer calibration at the cooking CCPs in your HACCP plan for crawfish and crabmeat. This deficiency was previously brought to your attention in the Form FDA 483 issued September 20, 2000.

The objectionable insanitary conditions listed on the Form FDA 483 are an indication that sanitation monitoring is inadequate. Your firm did not monitor the safety of the water that comes into contact with food nor the prevention of cross-contamination from insanitary objects to food and food contact surfaces. This is evidenced by the presence of a thick layer of filth residue, from previous operations, in the crawfish cook water, followed by the encrusting of this dirt and debris on cooked crawfish, and its subsequent contact with picking employees hands during picking operations. Your firm also failed to monitor the protection of food from adulteration with chemical contaminants, as evidenced by your use of a cleanser, on cooking equipment and picking tables, that has not been proven safe for food contact surfaces.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as copies of your modified HACCP plan, copies of examples of completed monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use

procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at 504-253-4519.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483